Pediatric Ethics Subcommittee
Open Meeting
September 10, 2004

Overview

On September 10, 2004 the first meeting of the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will be held. This subcommittee was established to address various pediatric ethical issues, including Institutional Review Board (IRB) referrals under Food and Drug Administration's (FDA) Subpart D regulations as well as joint referrals under both FDA and the Department of Health and Human Services (DHHS) Subpart D regulations. This meeting is being held to address a referral from the National Institute of Mental Health IRB of the protocol entitled "*Effects of a Single Dose of Dextroamphetamine in Attention Deficit Hyperactivity Disorder; A Functional Magnetic Resonance Study."* The subcommittee is to provide a recommendation as to whether the protocol should be approved under 21 CFR 50.54/45 CFR 46.407. That is, the committee is to consider whether the proposed clinical investigation/research either: (1) in fact satisfies the conditions of § 50.51/46.404, § 50.52/46.405 or § 50.53/46.406 or (2) meets the following conditions: (i) presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children; (ii) will be conducted in accordance with sound ethical principles; (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 50.55/46.408.

To prepare you for these deliberations, you will hear a series of presentations. The topics to be covered include: the Subpart D Expert panel process, charge to the committee, overview of the protocol, presentation by the Principal Investigator, comments from the National Institute of Mental Health IRB representative, and a summary of all public comments submitted. The subcommittee will then discuss the protocol as it relates to its approvability under 21 CFR 50.54/45 CFR 46.407.

Introduction

In April 2001, FDA published an interim rule to amend its regulations to provide additional safeguards for children enrolled in clinical investigations of FDA-regulated products. The interim rule was intended to bring FDA regulations into compliance with provisions of the Children's Health Act of 2000. This Act required that within 6 months of its enactment all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services be in compliance with HHS regulations providing additional protections for children involved as human subjects in research.

Both FDA and HHS regulations provide a process for an IRB to refer to FDA and/or HHS under § 50.54/§ 46.407 any protocols which the IRB does not believe meets the requirements of § 50.51/ 46.404, § 50.52/46.405 or § 50.53/46.406, and finds presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Under the Subpart D regulations, a clinical investigation/research may proceed if the Commissioner and/or Secretary find, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following an opportunity for public comment that certain conditions are met.

The Office for Human Research Protection (OHRP) and the FDA have been working to develop a unified and comprehensive process for Subpart D referrals under 21 CFR 50.54 and 45 CFR 46.407. We have agreed to utilize FDA's Pediatric Ethics Subcommittee and experts designated by OHRP to handle these referrals. The Pediatric Ethics Subcommittee will then present its deliberations to the full Pediatric Advisory Committee, which will then provide a recommendation to the Commissioner of the FDA and the Secretary of DHHS.

We understand this is a new process and we appreciate your assistance in participating in a newly defined approach for dealing with complex and difficult issues. Once we have completed this 1st referral cycle, your suggestions for improvements will be welcome. If you have any procedural questions prior to the meeting please feel free to contact the Office of Pediatric Therapeutics at 301-827-1996.

We look forward to your participation on September 10, 2004, as we embark on this important activity in pediatric research.

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